

REMARKS

In this office action the Examiner rejected claims 30-54 under 35 U.S.C. 112, second paragraph, as being for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 30 recites the broad recitation "contraceptive polymer is from the hydrogen class of polymers", and the claim also recites "particularly a mixture of styrene maleic anhydride copolymer and styrene maleic acid copolymer" which is the narrower statement of the range/limitation.

It is unclear which is supposed to be the invention. Is the claimed invention intended to be a composition comprising a contraceptive polymer from the hydrogen class of polymers or a composition comprising a mixture of styrene maleic anhydride copolymer and styrene maleic acid copolymer? Similarly, claim 30 recites broadly "an electrically conducting material", and also narrowly recites that the "said electrically conducting material is copper." Furthermore, claim 30 recites broadly "a magnetic material", and also narrowly recites that the "said magnetic material is iron." Accordingly, it is unclear which limitation is intended to be the limitation of the claimed invention.

In the present instance, claim 31 recites the broad recitation "styrene maleic acid copolymer and styrene maleic anhydride copolymer are taken in the ratio varying between 1.5:8.5 to 3:7", and the claim also recites "preferably 2:8" which is the narrower statement of the range/limitation. Accordingly, it is unclear which limitation is intended to be the limitation of the claimed invention.

In the present instance, claim 34 recites the broad recitation "electrical conducting material is take between 3-8%", and the claim also recites "preferably between 4-6%" and "more preferably about 5%" which is the narrower statement of the range/limitation. Accordingly, it is unclear which limitation is intended to be the limitation of the claimed invention.

In the present instance, claim 35 recites the broad recitation "magnetic material is taken between 6-15%", and the claim also recites "preferably between 8-12%" and "more preferably about 10%" which are the narrower statements of the range/limitation. Accordingly, it is unclear which limitation is intended to be the limitation of the claimed invention.

In the present instance, claim 36 recites the broad recitation "microsize particles... is about 0.005 to 20", and the claim also recites "preferably about 0.5 to 15~" which is the narrower statement of the range/limitation. Accordingly, it is unclear which limitation is intended to be the limitation of the claimed invention.

In the present instance, claim 37 recites the broad recitation "microsize particles ... is about 0.005 to 15 ~", and the claim also recites "preferably about 0.5 to 15~" which is the narrower statement of the range/limitation. Accordingly, it is unclear which limitation is intended to be the limitation of the claimed invention.

In the present instance, claim 48 recites the broad recitation "solvent medium", and the claim also recites "particularly... dimethyl sulphoxide" which is the narrower statement of the range/limitation. Accordingly, it is unclear which limitation is intended to be the limitation of the claimed invention.

In the present instance, claim 48 recites the broad recitation "inert atmosphere", and the claim also recites "preferably nitrogen"

which is the narrower statement of the range/limitation. Accordingly, it is unclear which limitation is intended to be the limitation of the claimed invention.

In the present instance, claim 49 recites the broad recitation "magnetic material", and the claim also recites "preferably coated magnetic material" which is the narrower statement of the range/limitation. Accordingly, it is unclear which limitation is intended to be the limitation of the claimed invention.

Claim 30 is also rejected for being vague and indefinite because it refers to copper "in its pure form" and to iron "in its pure form." It is unclear what Applicant intends to mean by these phrases. Applicant could intend to limit the claims to a composition comprising copper, which has been purified in a particular manner, or Applicant could intend to limit the claims to copper that is in elemental form. Similarly, Applicant could intend to limit the claims to a composition comprising iron, which has been purified in a particular manner, or Applicant could intend to limit the claims to iron that is in elemental form. For examination purposes, this claim is interpreted as referring to elemental iron and elemental copper.

Claim 33 is rejected for being vague and indefinite because the phrase "each varies between 3 to 20%" is unclear. It is unclear if Applicant intends each to independently vary between 3 and 20% or if each is intended to have an identical weight percentage to the other, which is between 3 and 20%. Furthermore, the term "varies"

is, itself, unclear. It is not clear how a composition comprising a certain weight percentage of a component can have a varying amount of that component. It is Examiner's interpretation that Applicant intends for the claim to read that the amount of material is between 3 and 20%. For examination purposes, Examiner interprets the claim as reading upon: each being independently between 3 and 20%.

Claim 32 recites the limitation "said magnetic material is iron in the form of oxide". There is insufficient antecedent basis for this limitation in the claim.

Claim 47 recites the limitation "said external means". There is insufficient antecedent basis for this limitation in the claim.

Independent claim 48 recites the limitation "said magnetic material". There is insufficient antecedent basis for this limitation in the claim.

Independent claim 48 recites the limitation "said electrically conducting material". There is insufficient antecedent basis for this limitation in the claim.

Furthermore, claims 31-47 and claims 49-54 are rejected for depending on an indefinite claim. Each of the rejected claims is examined on the basis of the broadest possible interpretation of the claim. Therefore, the claims with broad limitations followed by narrow limitations are interpreted as being only limited to the broad limitations.

Applicant has amended the claims and added new claims 55 and 56 to eliminate the indefinite nature of the claims; therefore,

Applicant respectfully requests that the Examiner withdraw the rejection of claims 30-54 under 35 U.S.C.112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner also rejected claims 30-47 under 35 U.S.C. 103(a) as being unpatentable over Guha (USPN 5488075) in view of each of Young et al. (USPN 5817017), Riar, et al. (Andrologia, 1982, 14(6), 481). and Jakubek, et al. (GB 2 121 289 A).

To support the rejection the Examiner stated, Guha teaches the use of a styrene maleic anhydride copolymer with DMSO as a contraceptive (col. 1, lines 54-62). It is further taught that when injected into the vas deferens, the contraceptive copolymer hydrolyzes in the presence of water molecules in the spermatic fluid (col. 2, line 45-col. 3, line 7). Accordingly, it is Examiner's interpretation, that Guha teaches a composition comprising DMSO and a mixture of styrene maleic anhydride copolymer and the hydrolyzed copolymer thereof, namely styrene maleic acid copolymer.

Guha does not teach a composition further comprising a magnetic material and an electrically conducting material.

Young et al. teaches the use of magnetic particles within catheters and other medical devices, particularly those devices composed of organic polymers, for enhanced detectability when viewed using magnetic resonance imaging (col. 1, lines 26-57; col. 2, line 55-col. 5, line 59). Young et al. specifically teaches the use of

small iron, including elemental iron and iron oxides, particles of a size less than 20 ~m in catheters and other devices (col. 10, lines 42-63).

Riar et al. teaches that copper deposited into the vasa deferentia of animals is effective at achieving a male contraception for 9 months (bottom of page 490-top of page 491).

Jakubek et al. teaches the use of a polymer mixed with 1 to 30% weight of a powdered metal, such as copper, as a contraceptive. The powdered metal is distributed throughout the polymer material and has a particle size of 2 to 50 μ m. (Abstract.)

It would have been obvious to one of ordinary skill in the art to combine iron particles of a size less than 20~m with the DMSO/polymer composition taught by Guha because, as taught by Young et al., iron particles are useful for enhancing magnetic resonance viewing of polymeric medical devices. Furthermore, it would have been obvious of one of ordinary skill in the art to add copper to the composition because it is obvious to one of ordinary skill in the art to combine two compositions each of which is taught by the prior art to be individually useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Kerkhoven 205 USPQ 1069 (CCPA 1980). Therefore, it would have been obvious to combine copper particles in the size of 2 to 50~m to the afore mentioned composition because (1) copper is known to be, itself, capable of contraception, as taught by Riar et al. and (2) polymeric contraceptives which include metallic components, such as copper,

include said metallic components in particle sizes of 2 to 50~m, as taught by Jakubek et al. It would have been obvious to incorporate the copper particles into the composition as claimed herein, because the weight percentage of the copper particles claimed herein fall within the range taught by Jakubek et al.

One would have been motivated to combine iron and copper particles to the composition of Guha because of (1) an expectation of providing a means of locating said composition once it had been implanted into the body, as taught by Young et al., and (2) an expectation of success in preparing a composition capable of producing similar results in contraceptive behavior due to the ability of each component to individually affect contraception, as taught by Riar et al., respectively.

It is noted that since the macrosize particles are capable of being the same size as the microsize particles that a composition comprising particles of microsize, as defined by Applicant will, alone, meet the limitations of claims 37-39. It is also noted that a metal particles within a polymer composition will obviously be coated with that polymer. Furthermore, it is noted that Young et al. does not teach the desired weight percentage of the magnetic material. It is Examiner's position, however, that it would have been obvious to one of ordinary skill in the art to utilize the weight percentages of the magnetic material, as claimed herein, because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ

215 (CCPA 1980)."

Guhs, U.S. Patent number 5488075, does not mention or teach "Styrene maleic acid".

Hydrolysis of Styrene maleic anhydride is mentioned. But hydrolysis of Styrene maleic anhydride in the presence of proteins and amino acids as is present in the lumen of the vas deferens of the male or the fallopian tube of the female will not produce Styrene maleic acid. Instead a chemical complex having electrical charge conditions quite different from styrene maleic acid is formed as can be shown by electrophoretic mobility study. Such a complex does not interact with electrically conducting material for charge transfers as obtainable from styrene maleic acid and Copper interaction.

Moreover, if Styrene maleic acid alone is added to styrene maleic anhydride without the electrically conducting material for charge transfer the styrene maleic acid would penetrate the mucosa as well as the muscular layers of the vas deferens causing harm particularly leading to fibrosis which will make reversal impossible. Tissue penetration of compounds depends on electrical charge status. Additionally the contraceptive efficacy will decline because the denuded cells will coat the styrene maleic anhydride thus shielding it from the sperms and the action on the sperms will be reduced.

Hence anyone knowledgeable in the art will avoid mixing styrene maleic acid with styrene maleic anhydride for contraceptive placed in tubular ducts. Styrene maleic acid is not a standard chemical which can be readily available to a scientist for use in the field. For

instance SIGMA ALDRICH Company markets Styrene maleic anhydride but not Styrene maleic acid. So the thought of taking styrene maleic acid in the contraceptive will not be obvious. Styrene maleic acid has to be specially prepared for use in the contraceptive.

When Styrene maleic anhydride is prepared for contraceptive purpose care has to be taken to avoid any hydrolysis and conversion to styrene maleic acid by moisture. So the art described by patent US 5488075 requires avoiding styrene maleic acid.

The Examiner stated, "Young et al. teaches the use of magnetic particle within catheters ..."

Young et al (US5817017) do mention paramagnetic particles only for the purpose to "interact with the water protons of the surrounding patient's body to provide image enhancement" Young et al. do not mention imaging enhancement by any means other than the water proton interaction. Hence the use is limited to Magnetic Resonance Imaging. The specific manner of use of the paramagnetic particle limits its value to Magnetic Resonance Imaging.

The particles in the present patent application can be imaged not only by Magnetic Resonance Imaging but also by:

a. Measuring the magnetic field of the particles with sensor placed outside the body. Such a sensor can be of a few cubic centimeters in dimension without the complexity of the large sized Magnetic Resonance Imaging. No "Resonance" is involved in such a measurement.

b. The particles used in the present patent application function even without their magnetic property enabling Ultrasonic detection mentioned in the patent application.

The magnetic particles in the Young et al. patent serve only for imaging. The particles in the present patent application serve also for mechanical propulsion under the influence of an external magnetic field.

The Examiner also stated,

"Furthermore it would have been obvious of one of ordinary skill in the art to add copper to the composition..." .

Riar et al. uses copper for its chemical properties embedded in vas deferens wall. The present patent application uses "electrically conducting material" which could be a material other than copper.

In the present patent the electrical conduction property is used for induction heating for removal of the contraceptive. Such an action would be obtained with a material which conducts electricity but is not copper. In Riar et al. contraceptive effect is dependent on the chemical properties of copper.

Hence Riar et al.'s disclosure does not lead to an obvious use of an electrically conducting material in a contraceptive formulation.

Further, the Examiner added, "...Jakubek et al... It would have been obvious to incorporate the copper particles ..."

With respect to the Examiner's comment about the obviousness of incorporating copper, Jakubek et al. cover use as an intrauterine device. The disclosure does not teach any usage in the fallopian tube.

Use of copper in the fallopian tube is therefore not obvious from Jacubek disclosure.

Also Jacubek's disclosure does not teach heating of the copper for removal. Intrauterine devices are removed by pulling on a string.

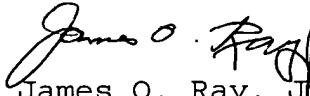
Action of copper in the intrauterine device is on account of its chemical properties and the disclosure does not lead to the concept of usage for a physical property which in this case is electrical conductivity .

Since neither Juha, Young et al., Riar et al. nor Jakubet et al. Teach or suggest the use of chemicals such as styrene maleic acid or copper as they are used in the present invention, Applicant respectfully requests that the Examiner withdraw the rejection of claims 30-47 under 35 U.S.C. 103(a) as being unpatentable over Guha (USPN 5488075) in view of each of Young et al. (USPN 5817017), Riar, et al. (Andrologia, 1982, 14(6), 481). and Jakubek, et al. (GB 2 121 289 A). Applicant further notes that the Examiner required four different prior art references which would strongly suggest that it would not be very obvious to one with ordinary skill in the art to come up with the present invention.

In view of the amendment to the claims and the discussion supra it is believed that claims 30-56 are patentable. Therefore, Applicant believes that this application is now in condition for allowance and such allowance by the Examiner is respectfully requested.

In the event the Examiner has further difficulties with the examination and/or allowance of the application, the Examiner is invited to contact the undersigned agent for applicant by telephone at (412) 380-0725, if necessary, to resolve any remaining questions or issues by interview and/or Examiner's Amendment as to any matter.

Respectfully submitted,
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